REMARKS

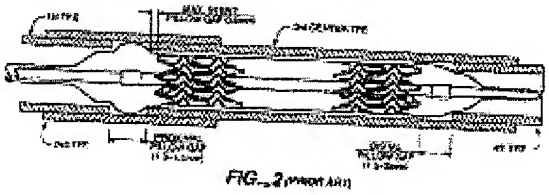
This paper is filed in response to an Office action mailed on January 24, 2007. In the Office action, the withdrawal of claims 1-8 and 21-30 is acknowledged and pending claims 9-20 are rejected. In view of the Examiner's comments, applicant has amended claim 9 to specify that the first inner diameter of the stepped enclosure is greater than the second inner diameter, which is consistent with the specification and drawings. No new matter is added thereby.

In view of the amendments and remarks submitted herewith, reconsideration and allowance of all pending claims are respectfully requested.

Rejections Under 35 U.S.C. § 102(e)

In the Office action, claims 9 and 13 are rejected as being anticipated by U.S. Patent No 6,948,223 ("Shortt"). In response, applicant has amended claim 9 to clarify that the diameter of the balloon disposed distally of the stent is not greater than the diameter of the stent. This amendment is supported by paragraph [0013] and Figures 5-8 of the application. No new matter is added thereby.

Moreover, applicant respectfully submits that amended claim 9 now includes one or more elements that is not disclosed or suggested by Shortt. Shortt discloses a process for mounting a stent on a balloon using four sheaths as shown below:



While the larger sheath on the left and the larger sheath on the middle/right are similar to the first and second sections the claimed stepped enclosure, the Shortt process further requires the use of two additional sheaths to form a proximal balloon pillow on the left and a distal balloon pillow on the right as shown above. Consequently, the process disclosed in Shortt requires the balloon disposed distally of the stent to have a maximum outer diameter *greater* than the diameter of the distal end of the stent, which is in contrast to

the method of amended claim 9 that requires the maximum outer diameter of the distal section of the balloon to be *no greater* than the initial outer diameter of the stent.

All of the other Shortt embodiments have distal balloon pillows bulging from the distal end of the stent with maximum outer diameters greater than the stent. Therefore Shortt does not teach or suggest a maximum outer diameter of the distal section of the balloon that is no greater than the initial outer diameter of the stent.

Moreover, in the Office action, the Patent Office asserts that Shortt discloses a method for fabricating a balloon catheter stent deployment system comprising, among other things, placing a stent over a balloon catheter and crimping the stent onto the balloon

Applicant respectfully disagrees with this assertion. Both Shortt's improved method and the process of FIG. 2 reprinted above comprises a first step of crimping a stent down to a required size (column 2, lines 16-17 and 54-55). Thereafter, the crimped stent is loaded "onto the delivery system" ... "and positioned on the balloon" (column 2, lines 22-24 and 55-57). Clearly, Shortt does not teach or suggest *crimping* of the stent onto the balloon.

As Shortt does not disclose or suggest a method of fabricating a balloon catheter comprising crimping a stent onto a balloon, wherein the maximum outer diameter of the balloon disposed distally of the stent is no greater than the initial outer diameter of the stent, Shortt fails to teach each and every element of the amended claim 9, and therefore does not anticipate amended claim 9. As amended independent claim 9 is not anticipated by Shortt, it follows that dependent claim 13 is not anticipated by Shortt. Accordingly, the anticipation rejection based on Shortt is traversed and must be withdrawn

Rejections Under 35 U.S.C. § 103(a)

In the outstanding Office action, claim 12 is rejected as being obvious over Shortt in view of U.S. Patent No. 5,147,302 ("Euteneuer"); claims 9 and 18 are rejected as being obvious over Shortt; claims 10-11 are rejected as being obvious over Shortt in view of U.S. Patent No. 5,704,845 ("Miraki"); claim 12 is rejected as being obvious over Shortt in view of International Application No. WO02/066095 ("Johnson"); claims 14-15 are rejected as being obvious over Shortt in view of U.S. Patent No. 6,629,350 ("Motsenbocker"); and finally claims 16-17 and 19-20 are rejected as being obvious over Shortt in view of U.S. Patent 5,836,965 ("Jendersee").

However, applicant respectfully submits that with the amended set of claims, each one of these obviousness rejections fails to meet the standards of MPEP §2142 as each rejections fails to establish a *prima facie* case of obviousness. Under §2142,

> [t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

Thus, MPEP § 2142 requires the prior art reference or references when combined to teach or suggest *all the claim limitations*. As noted above, Shortt fails to teach or suggest, either through the improved method or the prior art disclosed in the specification, a method of fabricating a balloon catheter comprising crimping a stent onto a balloon, wherein the maximum outer diameter of the distal section of the balloon is no greater than the initial outer diameter of the stent, and therefore the obviousness rejection of claims 9 and 18 is overcome and should be withdrawn.

The Office action also rejects claim 12 as being obvious over Shortt in view of Euteneuer. However, Euteneuer is merely cited for the proposition that it discloses a protective sleeve or sleeves 50, 60 that are placed over the balloon during sterilization. Euteneuer does not teach or suggest a stent/balloon combination for the use of any portion of the balloon to serve as the protective element for a stent Thus, Euteneuer cannot serve as a secondary reference to supplement the deficiencies of Shortt. Therefore, the obviousness rejection in claim 12 is traversed and should be withdrawn.

The Office action further rejects claims 10-11 as being obvious over Shortt in view of Miraki. However, Miraki is only cited for the proposition that it discloses the use of a protective sheath or sleeve after the stepped enclosure is removed. In other words, Miraki only teaches the use of a protective sheath for packaging purposes. Miraki teaches nothing about the formation of a protective element for the stent from a proximal or distal section of the balloon. Therefore, Miraki cannot supplement the deficiencies of Shortt and the obviousness rejection of claims 10-11 is overcome and must be withdrawn.

The Office action also rejects claim 12 as being obvious over Shortt in view of Johnson. However, Johnson is merely cited for providing flared ends to molds used for forming balloon catheter stent deployment systems in order to facilitate the loading of a balloon/stent assembly into the mold. Moreover, although Johnson discloses the use of the mold to form balloon shoulders having a diameter greater than the stent, the balloon shoulders, much like the balloon pillows disclosed in Shortt, are located on both the proximal and the distal ends of the stent. Therefore, the combination of Johnson with Shortt falls short of teaching each and every limitation of the rejected claim. Accordingly, applicant submits that this rejection is traversed and must be withdrawn.

The Office action then rejects claims 14-15 as being obvious in view of Shortt in view of Motsenbocker. However, Motsenbocker only teaches a crimping element Motsenbocker teaches nothing about the stepped enclosure recited in independent claim 9 which Shortt fails to completely teach or suggest. Motsenbocker teaches nothing about the shapes and dimensions of a balloon disposed proximally or distally of a stent. Accordingly, the obviousness rejection of claims 14-15 based upon the combination of Shortt and Motsenbocker is overcome and must be withdrawn

Finally, the Office action rejects claims 16-17 and 19-21 as being obvious over Shortt in view of Jendersee. As discussed in applicant's previous response to an Office action dated November 15, 2006, Jendersee fails to teach or suggest the use of a stepped enclosure with a first larger diameter that is placed over a proximal section of the balloon disposed proximally of the stent, and with a second smaller diameter that is placed over the stent to keep the stent from expanding upon inflation of the balloon. Jendersee fails entirely to teach or suggest any type of enclosure that allows a proximal section of the balloon, to expand to a diameter that is larger than the unexpanded outer diameter of the stent. Jendersee fails entirely to teach or suggest any method in creating a protective pillow from the proximal section of the balloon that serves to protect the stent upon retraction of the assembly during a procedure. As a result, the combination of Shortt and Jendersee falls short in teach each and every element of the rejected claims. Accordingly, this is rejection is traversed and must be withdrawn.

In light of all the foregoing, Applicants respectfully submit that each of the currently pending claims, i.e. claims 9-20, is in a condition for allowance and respectfully solicit same. If a telephone call would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney at the number listed below.

Dated: May 23, 2007

Respectfully submitted,

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